Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Westmead Hospital

Title	*The Australian Colonic LSL Endoscopic Resection Study. A prospective, multicentre observational study*
Short Title	*The ACE Study*
Protocol Number	*2.0*
Principal Investigator	*Professor Michael Bourke*
Associate Investigator(s)	*Dr Nicholas Burgess* *Dr Stephen Williams* *Dr David Tate*
Location	*Westmead Hospital*

Part 1 What does my participation involve?

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1 Introduction

You are invited to take part in this research project, The Australian Colonic LSL Endoscopic Resection Study. This is because you have been referred to have a large polyp removed at colonoscopy. The research project is aiming to answer questions about the types of patients who develop polyps and the polyps themselves, as well as examining ways of improving the procedure and reducing complications.
This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to the tests and research that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The purpose of this research is to investigate patient outcomes following removal of large polyps. Polyps are growths of the inner lining of the bowel that have the potential to become bowel cancer if not removed. Removal of large flat polyps from the large bowel (colon) using a colonoscope and a technique known as endoscopic mucosal resection or "EMR" has been shown to be safe and effective when performed at an expert centre. In the past the only alternative for removal of these large polyps was by a surgical operation requiring several days in hospital, however now, the majority of patients can avoid surgery and have their polyp removed by EMR as a day case.

Large polyps are uncommon occurring in only 1% of all colonoscopies. This makes them difficult to study because large numbers are needed to answer research questions and many endoscopy centres will only see a few a year. Because of this, there are many unanswered questions about the types of patients who develop polyps and the polyps themselves, and we are continually looking at ways of reducing complications and improving the EMR procedure. By enrolling many patients from centres all around Australia specialising in the removal of large polyps, we can obtain reliable information on polyps and their removal and improve the procedure for future patients.

This research has been initiated by the study doctor, Professor Michael Bourke.

3 What does participation in this research involve?

Before the colonoscopy procedure, one of the researchers will discuss the study with you, check that you are suitable for the study and answer any questions you may have. Once all the questions are answered, if you agree to participate, you will be asked to complete a consent form and provisionally enter the study.

If a large flat polyp over 20 millimetres in size is found during colonoscopy, you will enter the study and data will be collected on the polyp and aspects of the procedure. If a polyp fitting this description is not found, then you will not enter the study. The rest of the procedure will continue as normal. Images of the polyp and the procedure are taken as part of usual clinical care and stored in the medical record. The polypectomy procedure may be video recorded however all patient details are de-identified. Unless something unexpected occurs, you will be able to go home on the same day. After the procedure, the specimens removed will be carefully looked at under the microscope by a pathologist and the results analysed.

If enrolled in the study you will be contacted 2 weeks after the initial procedure by telephone to provide information on any complications or problems you may have had. All patients as part of their usual care and regardless of whether they are enrolled in the study require a repeat colonoscopy 4-5 months after the initial procedure to check that the polyp has not grown back, then following this at intervals of 12 months, 3 years and 5 years. Information is collected at each of these points if you are enrolled in the study. The research project duration is 10 years. You or your referrer may be contacted to check whether follow up procedures have been performed and their outcomes at these time points. The research is monitored by an independent safety monitoring board.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid. You will be reimbursed for any reasonable travel expenses.

4 What do I have to do?

To participate in the study you will agree to be contacted 2 weeks after the initial procedure by telephone to provide information on any complications or problems you may have had. Data will be recorded at any scheduled repeat colonoscopies you undergo at 4-5 months, 12 months, 3 years and 5 years. You are not required to do anything at these times, although we may contact you to check whether or not you have had procedures completed.

5 Other relevant information about the research project

The study is part of a national collaborative study coordinated by Australian researchers at 16 different Australian sites. It involves collecting data from the procedures that patients undergo in the normal, standard of care treatment for large colon polyps. It is expected that 4000-5000 patients well be enrolled over the course of the study.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.
Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Westmead Hospital.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. If you decide not to participate, you will undergo the same procedure, however research data will not be recorded. it will not affect the treatment you receive now or in the future.

8 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. Your participation may improve outcomes for future patients undergoing the procedure.

9 What are the possible risks and disadvantages of taking part?

There are no additional risks associated with this study as it is only recording information about your procedure.

Colonoscopy procedures are not recommended in pregnant women. Because of this, it is important that research project participants are not pregnant at the time of the initial procedure, or at the time of any follow up procedure. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project.

If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will advise you on any alterations to surveillance procedures as a result of the pregnancy. You must not undergo colonoscopy procedures while pregnant.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my test samples?

The tissue sample/s you provide during the study are analysed and stored as part of your routine clinical care, and are processed in an identical way to patients that are not enrolled in the study. The tissue sample/s you provide during the study will be stored securely at the completion of the study according to standard hospital policy. Tissue sample/s stored by the hospital are stored in an identifiable way, however any data stored for research purposes will be re-identifiable (coded).

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

13 What if I withdraw from this research project?

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. Please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. You will be required to complete and sign a withdrawal of consent form.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

As the research study is an observational data collection study it is unlikely to be unexpectedly terminated.

15 What happens when the research project ends?

At the completion of the research project, follow up will be with your referring doctor. We plan to discuss/publish the results in international peer reviewed journals and present the data at international conferences. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Of the people treating you, only the study researchers and nursing staff involved in your care will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will be coded by your study staff, and will not be labelled with or identified by your name, picture or any other information that can directly identify you. Only the researchers named above will have access to your details and results that will be held securely by the research team at Westmead Hospital, Sydney. Data will be stored for 15 years after completion of the study Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. If any case is highlighted for research or educational purposes, all identifying details such as name or date of birth will be removed.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

If you have a complaint regarding your treatment as a participant of the study, you should contact the complaints contact person (details below)

If you suffer any injuries or adverse events as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or adverse event, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research project is being conducted by Professor Michael Bourke. There are no financial sponsors of the project. There are no expected financial benefits that will arise from this research and no member of the research team will receive a personal financial benefit from involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Western Sydney Local Health District.
This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor Professor Michael Bourke on 02 9845 5555.

Clinical contact person

Name	Professor Michael Bourke
Position	Director of Endoscopy, Westmead Hospital
Telephone	(02) 9633-5953
Email	reception@citywestgastro.com.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Position	Patient Advice and Liaison Service
Telephone	02 8890-7014

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	WSLHD Human Research Ethics Committee
HREC Executive Officer	Kellie Hansen
Telephone	(02) 8890-8183
Email	wslhd-researchoffice@health.nsw.gov.uk

Local HREC Office contact (Single Site -Research Governance Officer)

Name	Margaret Piper
Position	Research Governance Officer
Telephone	(02) 8890-9634
Email	wslhd-rgo@health.nsw.gov.au

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Associate Investigator(s)	*Dr Nicholas Burgess* *Dr Stephen Williams* *Dr David Tate*
Location	*Westmead Hospital*

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I understand that, if I decide to discontinue the research project treatment a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

Title	*The Australian Colonic LSL Endoscopic Resection Study. A prospective, multicentre observational study*
Short Title	*The ACE Study*
Protocol Number	*2.0*
Coordinating Principal Investigator/ Principal Investigator	*Professor Michael Bourke*
Associate Investigator(s)	*Dr Nicholas Burgess* *Dr Stephen Williams* *Dr David Tate*
Location	*Westmead Hospital*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Westmead Hospital

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.